

Serial No.: 09/899,780  
Docket No.: 70012590-04

### III. AMENDMENTS TO THE CLAIMS

Please cancel Claims 19-22.

1-12. (Canceled)

---

13. (Original) A method of manufacturing a composition comprised of effector T lymphocytes generated by:

- a. vaccinating a patient with a vaccine comprised of the patient's own malignancy and an immunologic adjuvant;
- b. removing primed peripheral blood T of the patient;
- c. stimulating the primed T lymphocytes to differentiate into effector lymphocytes in vitro; and
- d. stimulating the effector T lymphocytes to proliferate in vitro.

D 7  
14. (Original) The method in claim 13 wherein the immunologic adjuvant is GM-CSF.

15. (Original) The method in claim 13 wherein the removal step is performed by leukapheresis.

16. (Original) The method in claim 13 wherein the differentiation step is performed using anti-CD3.

17. (Original) The method in claim 13 wherein the proliferating step is performed using IL-2.

18-22. (Canceled)

Serial No.: 09/899,780  
Docket No.: 70012590-04

**Please add the following new claims:**

- D7  
al
- 23. (new) The method in claim 13 wherein said patient's own malignancy comprises breast cancer.
  - 24. (new) The method in claim 13 wherein said patient's own malignancy comprises astrocytoma.
  - 25. (new) The method in claim 13 wherein said patient is vaccinated at multiple body sites.
  - 26. (new) The method in claim 13 wherein the patient is vaccinated with at least  $5 \times 10^6$  malignant cells.
  - 27. (new) The method in claim 13 wherein said patient is vaccinated at the time of initial diagnosis.
  - 28. (new) The method in claim 13 further comprising the step of irradiating said patient's malignancy prior to said vaccination step.

---

**IV. REMARKS**

**A. Specification**

Pursuant to paragraph 3 of the Office Action, Applicant has amended the application to reference Applicant's prior patent. In addition, pursuant to Paragraph 6 of the Office Action, Applicant has amended the specification to capitalize any trademarks as requested by the Examiner. In addition, Applicant has indicated ® or ™ where appropriate.

**B. Oath/Declaration**

Pursuant to Paragraph 4 of the Office Action, Applicant is submitting a supplemental oath/declaration.

Serial No.: 09/899,780  
Docket No.: 70012590-04

**C. Drawings**

Applicant acknowledges the Examiner's request to submit formal drawings in accordance with the draftperson's suggestions. In response, Applicant encloses a Submission of Corrected Drawings. Applicant respectfully requests approval of the drawings.

**D. Section 112**

In paragraph 7-8, the Examiner rejected Claims 19-22 as being indefinite under 35 U.S.C. § 112 as for depending upon a now-cancelled claim (Claim 18). In response, Applicant has cancelled these claims. Withdrawal of the Section 112 rejection is respectfully requested.

**E. Claim Rejections under Section 102**

In paragraph 9-10 of the Office Action, the Examiner rejected Claims 13-17 and 19-22 as anticipated under 35 U.S.C. § 102(b) by Babbitt et al., U.S. Patent No. 5,766,920 ("the Babbitt Patent"). Applicant respectfully traverses the rejection.<sup>1</sup>

First, the Babbitt Patent does not teach or suggest a vaccination step as recited in Applicant's claimed invention. As such, none of the T lymphocytes removed from the patient are "primed" as recited in Applicant's claimed invention. Instead, the Babbitt Patent teaches a process which involves merely "removing a patient's mononuclear cells and exposing the cells in vitro to substances which enhance the immune function of the cells." See column 2, line 15-19. In particular, mononuclear cells (including lymphocytes) are removed from the patient and stimulated with OKT3. See column 2, lines 23-44. These cells are not "primed." Indeed the Babbitt Patent states that upon exposure to the OKT3, the cells then become "immunoreactive" such that they "possess an enhanced capacity to proliferate and produce cytokines upon further

---

<sup>1</sup> Applicant has also added several new dependent claims. Now new matter has been added by these amendments. Support for these amendments is as follows: Claim 23 (original Claim 6); Claim 24 (original Claim 7); Claim 25 (original Claim 9); Claim 26 (§ 0051); Claim 27 (original Claim 10); Claim 28 (§ 0050).

Serial No.: 09/899,780  
Docket No.: 70012590-04

stimulation." See column 2, lines 59-60. The cells require "further exposure to an immune stimulant . . . such as a tumor cell . . . to achieve full immunologic effector function." See column 3, lines 7-12 (emphasis added). These cells may be "reinfused into the patient to enhance the patient's immune responses." See column 2, line 15-21.

In marked contrast, Applicant's Claim 13 recites: (1) vaccinating a patient with a vaccine comprised of the patient's own malignancy and an immunologic adjuvant; (2) removing primed T lymphocytes from the peripheral blood of the patient; (3) stimulating the primed T lymphocytes to differentiate into effector lymphocytes in vitro; (4) stimulating the effector T lymphocytes to proliferate in vitro; and (5) infusing the effector T lymphocytes back into the patient. Applicant respectfully submits that the Babbitt Patent fails to teach the vaccination step or removing the primed T lymphocytes from the peripheral blood of the patients. Instead, as discussed above, because there is no vaccination, the Babbitt Patent teaches a method whereby non-specific mononuclear cells are removed from the patient and stimulated with an non-specific immunogen (e.g., OKT3).

Applicant respectfully submits Claim 13 and all claims depending therefrom are not anticipated by the prior art because the vaccination step and the removal of primed T lymphocytes is not taught or suggested by the Babbitt Patent.

## V. CONCLUSION

In view of the present amendments to Applicant's claims and corresponding remarks contained herein, reconsideration and allowance of the application by the Examiner is requested. Applicant submits that the independent claims and the claims depending therefrom are patentable over the art cited by the Examiner and are in condition for allowance, which action is hereby respectfully requested. The art applied by the Examiner has been reviewed by Applicant and is believed not to anticipate or render obvious any claims in the application.

Serial No.: 09/899,780  
Docket No.: 70012590-04

Respectfully submitted,

By: 

Lana M. Knedlik, Reg. No. 42,748  
STINSON MORRISON HECKER LLP  
1201 Walnut Street, Suite 2800  
Kansas City, MO 64106-2150  
Telephone: (816) 842-8600  
Facsimile: (816) 691-3495  
Attorney for Applicant